The total FY 2001 application fee revenue is estimated by multiplying the adjusted application fee rate ($309,647) by the equivalent number of applications projected to qualify for fees in FY 2001 (163.6), for a total estimated application fee revenue in FY 2001 of $50,658,249. This is the amount of revenue that FDA is also expected to derive both from establishment fees and from product fees.

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of the PDUFA II, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in the PDUFA II fee revenue. To date, collections for FY 1998 total $117,446,776—a total of $324,776 in excess of the appropriation limit. This is the only fiscal year since 1997 in which FDA has collected more in the PDUFA II fees than Congress appropriated.

FDA also has requests for waivers or reductions of FY 1998 fees pending that, if granted, would eliminate the excess collections. For this reason FDA is not reducing its FY 2001 fees to offset excess collections at this time. An offset will be considered next year, when fees for FY 2002 are established, if FDA still has collections in excess of appropriations for FY 1998 after the pending requests for FY 1998 waivers and reductions have been resolved.

V. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2000, the establishment fee was based on an estimate of 318 establishments subject to fees. For FY 2000, 372 establishments qualified for and were billed for establishment fees, before all decisions on requests for waivers or reductions were made. FDA estimates that a total of 25 establishment fee waivers or reductions will be made in FY 2000, for a net of 347 fee-paying establishments, and will use this number for its FY 2001 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($50,658,249), by the estimated 347 establishments, for an establishment fee rate for FY 2001 of $145,989 (rounded to the nearest dollar).

B. Product Fees

At the beginning of FY 2000, the product fee was based on an estimate that 2,262 products would be subject to product fees. By the end of FY 2000, 2,369 products qualified and were billed for product fees before all decisions on requests for waivers or reductions were made. Assuming that there will be about 55 waivers and reductions made, FDA estimates that 2,314 products will qualify for product fees in FY 2000, after allowing for waivers and reductions, and will use this number for its FY 2001 estimate. Accordingly, the FY 2001 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($50,658,249) by the estimated 2,314 products for a product fee rate of $21,892 (rounded to the nearest dollar).

VI. Adjusted Fee Schedule for FY 2001

The fee rates for FY 2001 are set out in table 2 of this document:

TABLE 2.

Fee Category	Fee Rates for FY 2001
Applications	
Requiring clinical data	$309,647
Not requiring clinical data	$154,823
Supplements requiring clinical data	$154,823
Establishments	$145,989
Products	$21,892

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under the PDUFA II that is submitted after December 31, 2000, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee ID number on your check. Your check can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Food and Drug Administration (360909) Mellon Client Service Center rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This is a new Mellon Bank Address for courier delivery only.)

Please make sure that the FDA P.O. Box number (PO Box 360909) is on the enclosed check.

FDA will bill applicants who submitted lower application fees from October 1 to December 31, 2000, for the difference between the amount they submitted and the amount specified in the Adjusted Fee Schedule for FY 2001.

B. Establishment and Product Fees

By December 31, 2000, FDA will issue invoices for establishment and product fees for FY 2001 under the new Adjusted Fee Schedule. Payment will be due by January 31, 2001. FDA will issue invoices in October 2001 for any products and establishments subject to fees for FY 2001 that qualify for fees after the December 2000 billing.

Dated: December 7, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31949 Filed 12–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1632]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#117) entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMP's) submitted to the European Union, Japan, and the United States.

DATES: Submit written comments concerning the draft guidance to ensure their adequate consideration in preparation of the final document by January 17, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6524, e-mail: candres1@cvm.fda.gov.

Regarding the guidance document: Neal Bataller, Center for Veterinary Medicine (HFV–214), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0163, e-mail: nbatalle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically-based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the approval of VMP's in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on AER's

The VICH Steering Committee held a meeting on June 15, 2000, and agreed that the draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24) should be made available for public comment.

The draft guidance is intended to describe the harmonized and common systems, common definitions, and standardized terminology within pharmacovigilance. Harmonization of those elements between the VICH regions facilitates the reporting responsibilities for the marketing authorities or drug sponsors, many with worldwide activities. More specifically, the draft guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. The draft guidance describes the various components of information flow within the pharmacovigilance system. Finally, the draft guidance defines data elements that are sufficiently comprehensive to cover complex reports from most sources for the purpose of electronic transmission. (This information collected is authorized by OMB Control No. 0910–0012).

III. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' or phrases such as ''minimum standards'' or ''minimum needed'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

The draft guidance represents the agency's current thinking on the management of AER's of approved new animal drugs. This draft guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation

at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final guidance by January 17, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 8, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32056 Filed 12–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1629]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of two draft guidances for industry (Nos. 113 and 114, respectively) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written comments on the draft guidance documents by January 17, 2001, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance documents entitled ''Effectiveness of Anthelmintics: Specific Recommendations Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the draft guidances to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

You may submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the VICH: Sharon Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–2977, e-mail: candres1@cvm.fda.gov.

Regarding the guidance documents: Thomas Letonja (HFV–135), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical recommendations for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Anthelmintics

The VICH Steering Committee held a meeting from June 14 through 16, 2000, and agreed that the two draft guidance documents entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21) should be made available for public comment.

The two draft guidances, VICH GL20 and VICH GL21, should be read in conjunction with the ''Effectiveness of Anthelmintics: General Recommendations (EAGR)'' (64 FR 38445, July 16, 1999). The guidances for feline and poultry are part of the EAGR, and the aim of these two draft guidances is to: (1) Be more specific for certain issues not discussed in the general